UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PDL BIOPHARMA, INC. and EKR THERAPEUTICS, INC., Plaintiffs, v.	Civ. Action No. 07-1788 (KSH)
SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendant.	**OPINION**

Katharine S. Hayden, U.S.D.J.

Before the Court is Sun Pharmaceutical Industries Ltd.'s ("Sun") motion for reconsideration of the Court's March 31, 2009 opinion finding infringement by Sun's ANDA product. The Court assumes familiarity with the relevant background and procedural facts in that decision. (D.E. 190.)

I. Sun's Reconsideration Motion

On this motion, Sun primarily argues that the Court improperly found infringement based on a comparison of the accused ANDA product with Cardene I.V. (the commercial embodiment of EKR's '405 patent), rather than based upon a comparison of the accused product with the claims of the '405 patent. Sun also argues that the Court erroneously "adopted a theory of literal infringement." (Sun Recons. Mot. 6.) Sun submits that the '405 patent requires that Sun's product *simultaneously* (1) be isotonic; and (2) have at least 1.0 mg/ml nicardipine

hydrochloride. Sun contends that its ANDA product cannot literally infringe because it is not isotonic *in the ampul* and it is *below* 1.0 mg/ml *at the point of administration.* (Sun Recons. Mot. 8.)

Sun argues that the Court adopted a construction of the '405 patent claims that EKR's predecessor expressly disclaimed before the U.S. Patent and Trademark Office in its efforts to obtain the '405 patent. Sun claims that this error arises from the Court's "misunderstanding that literal infringement" was still at issue with respect to the concentration of nicardipine being "at least 1 mg/ml." Sun claims that EKR's counsel stated it was abandoning its literal infringement argument in an email to which the Court was not privy, as was excerpted in its briefing. (Sun Recons. Mot. 2.)

Sun submits that the Court's ruling erred in that it "adopt[ed] a claim construction that eliminated the 'at least 1 mg/ml' limitation of the '405 patent's claims—a limitation that EKR adopted specifically to ameliorate concerns expressed by the PTO in the prosecution history." (Sun Recons. Mot. 8.) Sun points to the patent prosecution history before the PTO because the examiner had rejected a claim for a "therapeutically effective amount of nicardipine" and did not specify a concentration. The examiner rejected that claim because prior art showed nicardipine at 0.6 mg/ml. Sun claims that because EKR earlier narrowed its claim to get a patent means that EKR cannot now recapture the excluded subject matter. The Court rejected this argument in its March 31 opinion, stating "because, with respect to the nicardipine concentration specification, Sun's ANDA product literally infringes in the ampul with a concentration of 2.5 mg/ml." (D.E. 190, p. 28).

II. Law Governing Reconsideration Motions

Local Civil Rule 7.1(i), which governs motions for reconsideration, provides:

> A motion for reconsideration shall be served and filed within 10 business days after the entry of the order or judgment on the original motion by the Judge or Magistrate Judge. A brief setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked shall be filed with the Notice of Motion.

D.N.J. Local Civil Rule 7.1(i). A motion under Rule 7.1(i) may be granted if: "(1) [A]n intervening change in the controlling law has occurred, (2) evidence not previously available has become available, or (3) it is necessary to correct a clear error of law or prevent manifest injustice." *North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995). "Relief by way of a motion for reargument is an extraordinary remedy that is to be granted very sparingly." *Capell v. Lowe's Home Imp. of Toms River*, 2005 WL 2373415, *2 (D.N.J. Sept. 27, 2005) (J. Thompson). "The local rule governing reconsideration does not contemplate a recapitulation of arguments considered by the court before rendering its decision." *Id.* The rule generally permits reconsideration only where dispositive factual matters or controlling decisions of law were presented to the court but were overlooked. *Id.* (internal citations omitted); *Khair v. Campbell Soup Co.*, 893 F. Supp. 316, 337 (D.N.J. 1995).

III. Discussion

A. Comparison of Sun's ANDA product to the '405 Patent's Claims

Sun's argument that the Court based its finding of infringement upon a comparison of Sun's ANDA product to Cardene I.V. rather than the '405 claims ignores the Court's focus on the '405 claims in its March 31, 2009 opinion and the findings made that each claim was met by Sun's ANDA product. First, on pages 6 and 7 of the March 31 opinion the Court recited the proper legal standard in observing that the patent claims alone vest the patent holder's right to exclude and that a finding of infringement requires that the accused product contains every

limitation as outlined in the patent claims. (D.E. 190.) And the Court properly focused on whether Sun's ANDA product met every limitation in the '405 claims.

On page 12, the Court set out how Sun's ANDA would use a buffer solution and sorbitol to stabilize its ANDA product just as is done under the '405 patent. On page 20, in addressing the specifics of Sun's infringement, the Court states that Sun's ANDA would infringe the '405 patent's claim 1 because the ANDA product has a nicardipine concentration of at least 1 mg/ml and an adequate non-chloride compound to render it isotonic. Likewise, on page 28, the Court found that Sun's product in the ampul is "literally" within the '405 patent's limitation in claims 1 and 3 of a concentration of 'at least' 1.0 mg/ml of nicardipine hydrochloride. Starting on page 24, under the doctrine of equivalents, the Court assessed the function, way, and result of the sorbitol in the '405 patent and the function, way, and result of the non-chloride compound in Sun's ANDA product. The Court found that both components, as parts of their respective compositions, served the same function, acted in the same way, and reached the same result (*i.e.* the ANDA product and the '405 patent). On page 31, the Court concluded that—under the doctrine of equivalents and via the function-way-result test—only insubstantial differences existed between the accused ANDA product to the '405 patent claims, and that assigning to health care providers the final step of making the formula isotonic was not enough to render the ANDA product non-infringing.

In sum, the Court properly analyzed whether the accused ANDA product infringed the '405 patent claims, and not the commercial embodiment, Cardene I.V. The Court only mentioned Cardene in discussing background and for similar purposes, none of which undercuts the comparison of the ANDA product to the '405 claims and supports the finding of infringement.

B. The Court Did Not Adopt a Claim Construction Eliminating the Nicardipine Concentration Limitation of the '405 Claims

Sun's reconsideration motion also relies upon an argument the Court rejected in the March 31 opinion that its ANDA product does not have "at least 1 mg/ml of nicardipine hydrochloride." Instead, the Court found that "[t]he fact that Sun's product in the ampul is *literally* well within the '405 patent's limitation in claims 1 and 3 of a concentration of 'at least' 1.0 mg/ml of nicardipine hydrochloride cannot seriously be disputed." The Court did not overlook this argument; it found in its March 31 opinion that Sun cannot opt to have its ANDA product's nicardipine concentration measured at the time of administration and simultaneously choose to assert that it is not isotonic in the ampul.

Sun also claims that because EKR's predecessor disclaimed a formula with a nicardipine concentration below 1.0 mg/ml in order to gain approval before the PTO, then it cannot now "recapture" that subject matter. Sun is contending that because its *diluted* formula is below that concentration, then EKR cannot "exclude" Sun by way of the doctrine of equivalents. As the Court ruled on page 28 of its March 31 opinion, Sun cannot wield the prosecution history here because its ANDA product is *not below* the 1.0 mg/ml nicardipine concentration level disclaimed by the '405 patent *but is instead above it* in the ampul (with a 2.5 mg/ml level). Thus, the Court properly found in its March 31 opinion that EKR is not attempting to impermissibly broaden the scope of the '405 patent. Sun's argument on this point is without merit.

C. EKR Did Not Abandon its Literal Infringement Argument

The email cited by Sun in its Reconsideration Motion brief does not have bearing on the issues before Court because it was not filed on the docket, was not part of a stipulation, was not approved by the Court, and was not before the Court on the summary judgment motion. Rather,

the email was an informal communication between counsel and did not act as a waiver of any rights.

IV. Conclusion

For the foregoing reasons, Sun's motion for reconsideration (D.E. 190) is denied. An appropriate order will be entered.

/s/ Katharine S. Hayden

Hon. Katharine S. Hayden
U.S. District Judge